

Application Serial No. 10/665,708

Confirmation No. 6892

Filed: September 18, 2003

Atty. Docket No. GP107-03.DV1

RESPONSE TO RESTRICTION REQUIREMENT & PRELIMINARY AMENDMENT

IN THE CLAIMS

If the restriction requirement is maintained, claims 1-12 are withdrawn and claims 13-20 are elected. Please amend Claim 13 as shown below.

1. (Withdrawn) A method of detecting *Mycobacterium* species present in a biological sample, comprising the steps of:

providing a biological sample containing nucleic acid from at least one *Mycobacterium* species comprising a *Mycobacterium* 16S ribosomal RNA (rRNA) or DNA encoding *Mycobacterium* 16S rRNA;

amplifying the *Mycobacterium* 16S rRNA or *Mycobacterium* DNA in an in vitro nucleic acid amplification mixture comprising at least one polymerase activity, and a combination of at least two primers having sequences selected from the group consisting of a first primer of SEQ ID NO:11 and a second primer that is an oligonucleotide consisting of 19 to 25 bases, containing 18 contiguous bases of SEQ ID NO:24 and three to seven bases 5' to the 18 contiguous bases of SEQ ID NO:24 to produce amplified *Mycobacterium* nucleic acid; and

detecting the amplified *Mycobacterium* nucleic acid by detecting a label associated with the amplified *Mycobacterium* nucleic acid.

2. (Withdrawn) The method of Claim 1, further comprising in the steps of:

adding to the biological sample at least one capture oligonucleotide that specifically hybridizes to the *Mycobacterium* 16S rRNA and an immobilized nucleic acid that hybridizes to the capture oligonucleotide under hybridizing conditions to produce a hybridization complex; and

separating the hybridization complex from other components of the biological

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sample before the amplifying step.

3. (Withdrawn) The method of Claim 1, wherein the amplifying step amplifies 16S rRNA or DNA encoding 16S rRNA from *M. tuberculosis* or a *Mycobacterium* other than *tuberculosis* (MOTT) species.

4. (Withdrawn) The method of Claim 1, wherein the amplifying step amplifies 16S rRNA or DNA encoding 16S rRNA from *M. abscessus*, *M. africanum*, *M. asiaticum*, *M. avium*, *M. bovis*, *M. celatum*, *M. chelonae*, *M. flavescens*, *M. fortuitum*, *M. gastri*, *M. gordonae*, *M. haemophilum*, *M. intracellulare*, *M. interjectum*, *M. intermedium*, *M. kansasii*, *M. malmoense*, *M. marinum*, *M. non-chromogenicum*, *M. paratuberculosis*, *M. phlei*, *M. scrofulaceum*, *M. shimodei*, *M. simiae*, *M. smegmatis*, *M. szulgai*, *M. terrae*, *M. triviale*, *M. tuberculosis*, *M. ulcerans* or *M. xenopi*.

5. (Withdrawn) The method of Claim 1, wherein the detecting step uses at least one probe that hybridizes specifically to the amplified *Mycobacterium* nucleic acid.

6. (Withdrawn) The method of Claim 5, wherein the detecting step uses at least one labeled probe that hybridizes specifically to the amplified *Mycobacterium* nucleic acid.

7. (Withdrawn) The method of Claim 5, wherein the detecting step uses a plurality of probes that hybridize specifically to the amplified *Mycobacterium* nucleic acid.

8. (Withdrawn) The method of Claim 1, wherein the amplifying step uses a combination of at least a first primer and a second primer, wherein the first primer is SEQ ID NO:11, and the second primer is

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selected from the group consisting of SEQ ID NO:21, SEQ NO:22, SEQ ID NO:23 and SEQ ID NO:24.

9. (Withdrawn) The method of Claim 8, wherein the amplifying step uses a combination of at least a first primer and a second primer, wherein the second primer is SEQ ID NO:21.

10. (Withdrawn) The method of Claim 8, wherein the amplifying step uses a combination of at least a first primer and a second primer, wherein the second primer is SEQ ID NO:22.

11. (Withdrawn) The method of Claim 8, wherein the amplifying step uses a combination of the first primer and the second primer, wherein the second primer is SEQ ID NO:23.

12. (Withdrawn) The method of Claim 8, wherein the amplifying step uses a combination of the first primer and the second primer, wherein the second primer is SEQ ID NO:24.

13. (Currently amended) A composition for amplifying in an in vitro amplification reaction a *Mycobacterium* 16S rRNA sequence or a DNA encoding the *Mycobacterium* 16S rRNA, comprising a combination of at least two oligonucleotides, wherein a first oligonucleotide contains a promoter sequence and a sequence that hybridizes to a *Mycobacterium* 16S rRNA or DNA encoding the *Mycobacterium* 16S rRNA sequence, and a second oligonucleotide is an oligonucleotide consisting of 19 to 25 bases, containing 18 contiguous bases contained in of SEQ ID NO:24 and three to seven bases 5' to the 18 contiguous bases contained in of SEQ ID NO:24.

14. (Previously presented) The composition of Claim 13, wherein the composition comprises:

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at least one first oligonucleotide having the sequence of SEQ ID NO:11, and

at least one second oligonucleotide having the sequence of any one of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23 and SEQ ID NO:24.

15. (Previously presented) The composition of Claim 14, wherein the composition comprises:

at least one first oligonucleotide of SEQ ID NO:11, and

at least one second oligonucleotide of SEQ ID NO:21.

16. (Previously presented) A kit containing one or more oligonucleotides having a sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, and SEQ ID NO:24.

17. (Previously presented) The kit of claim 16, further containing an oligonucleotide of SEQ ID NO:11.

18. (Previously presented) The kit of claim 17, containing

at least one first oligonucleotide of SEQ ID NO:11, and

at least one second oligonucleotide of any one of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23 or SEQ ID NO:25.

19. (Previously presented) The composition of Claim 14, wherein the composition comprises:

at least one first oligonucleotide of SEQ ID NO:11, and

at least one second oligonucleotide of SEQ ID NO:23.

20. (Previously presented) The composition of Claim 14, wherein the composition comprises:

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at least one first oligonucleotide of SEQ ID NO:11, and
at least one second oligonucleotide of SEQ ID NO:24.